

CLAIMS:

1. An assay device comprising an array of non-nucleic acid molecules wherein each molecule in the array, with the exception of a negative control, is capable of interaction with its respective binding partner putatively in a biological sample from an animal, avian species or plant wherein the pattern of interaction between the molecules and the binding partners is indicative of a normal condition or a disease condition or disorder or a propensity for the development of a disease condition or disorder.
2. An assay device comprising an array of non-nucleic acid molecules wherein each molecule in the array, with the exception of a negative control, is capable of interaction with its respective binding partner putatively in a chemical library, phage display library or environmental sample wherein the pattern of interaction between the molecules and the binding partners is indicative of the presence, type and/or amount of a particular binding partner in said sample.
3. An assay device according to claim 1 wherein the biological sample is from a human or non-human animal.
4. An assay device according to any one of claims 1 to 3 wherein the array comprises the formula:

$$\left[\begin{array}{cccc} \left[P_{x_1} \right]_{b_1}^{n_1} & \left[P_{x_2} \right]_{c_2}^{n_2} & \dots & \left[P_{x_j} \right]_{d_j}^{n_j} \end{array} \right]_z$$

wherein

P is a member of a binding group capable of interacting with a binding partner;

n_1, n_2, \dots, n_j represent different members of the binding group;

x_1, x_2, \dots, x_i represent different binding groups;

b, c and d represent the number of different members of the binding groups x_1, x_2, \dots, x_i ; respectively and wherein b, c and d may be the same or different and each is from about 0 to about 100 provided that at least one of b, c or d is not 0;

z is the total number of groups of molecules on the array and is from about 2 to about 2000.

5. An assay device according to claim 4 wherein the disease condition or disorder is cancer.
6. An assay device according to claim 4 wherein the antigen is a chemical in a chemical library or in an environmental sample or is a peptide, polypeptide or protein in a phage display library.
7. An assay device according to claim 4 wherein the array comprises immunoglobulins in discrete regions of the solid support and the binding partners are antigens expressed on the surface of a normal or cancer cell or are released by a normal or cancer cell or are present on a microbe, virus, parasite or other pathogen or is a chemical in a chemical library or in an environmental sample or is a peptide, polypeptide or protein in a phage display library.
8. An assay device according to claim 7 wherein the array comprises the formula:

$$\left[\begin{matrix} [q_{o_1}]^{m_1} \\ e \end{matrix} \begin{matrix} [q_{o_2}]^{m_2} \\ f \end{matrix} \dots \begin{matrix} [q_{o_k}]^{m_i} \\ g \end{matrix} \right]_y$$

wherein

q is an immunoglobulin specific for an antigen expressed on a normal cell or cancer cell or antigen released by a normal cell or cancer cell or an antigen present on a

- 79 -

microbe, virus, parasite or other pathogen or is a chemical in a chemical library or in an environmental sample or is a peptide, polypeptide or protein in a phage display library;

m_1 m_2 m_i represent members of the same immunoglobulin group which bind to different parts of the same antigen;

o_1 o_2 o_k represent different groups of immunoglobulins defined by specificity to different antigens.

e , f and g represent the number of different immunoglobulins within each of groups o_1 o_2 o_k , respectively and wherein e , f and g may be the same or different and each is from 0 to 100 provided that at least one of e , f and g is not 0;

y is the total number of groups of immunoglobulins on the array and is from about 2 to about 2000.

9. An assay device according to claim 8 wherein the immunoglobulins are monoclonal antibodies.

10. An assay device according to claim 8 or 9 wherein the immunoglobulins are specific for cluster of differentiation (CD) antigens and/or myeloid (MY) antigens and or lymphoid (LY) antigens expressed on leukemic cells.

11. An assay device according to claim 1 wherein the disease condition or disorder is a non-neoplastic disorder.

12. An assay device according to claim 11 wherein the disease or condition is a non-neoplastic disorder of the immune system.

13. An assay device according to claim 11 or 12 wherein the disease or condition is selected from an autoimmune disease such as Type 1 diabetes, multiple sclerosis, myasthenia gravis, pernicious anaemia, psoriasis, rheumatoid arthritis, scleroderma and systemic lupus erythematosus, infection by a pathogen such as a virus including HIV-1, Hepatitis virus, Epstein-Barr virus (mononucleosis), a microorganism or a malarial parasite, congenital

- 80 -

immunodeficiency, adverse reaction following bone marrow or tissue transplantation or chronic fatigue syndrome.

14. An assay according to any one of claims 1 to 13 wherein the molecules immobilized on the solid support are in an arrangement in the array such that upon interaction between the molecules and the binding partners, a differential pattern of density provides an identifiable signal.

15. A method for determining the presence of a disease condition or disorder or a propensity to develop a disease condition or disorder such as but not limited to cancer or a non-neoplastic disorder in an animal, avian species or plant, said method comprising obtaining a biological sample from said animal, avian species or plant comprising free binding partners or binding partners bound to a cell surface associated directly or indirectly with said disease condition or disorder and contacting said biological sample with a solid support comprising an array of non-nucleic acid molecules capable of binding to said binding partners wherein the pattern of interaction with the binding partners is indicative of the disease condition or disorder or a propensity to develop said disease condition or disorder.

16. A method according to claim 15 wherein the biological sample is from a human or non-human animal.

17. A method according to claim 16 wherein the array comprises the formula:

$$\left[\begin{array}{c} \left[P_{x_1} \right]_{b}^{n_1} \left[P_{x_2} \right]_{c}^{n_2} \dots \left[P_{x_j} \right]_{d}^{n_j} \end{array} \right]_z$$

wherein

P is a member of a binding group capable of interacting with a binding partner;

- 81 -

n_1, n_2, \dots, n_i represent different members of the binding group;

x_1, x_2, \dots, x_i represent different binding groups;

b, c and d represent the number of different members of the binding groups x_1, x_2, \dots, x_i ; respectively and wherein b, c and d may be the same or different and each is from about 0 to about 100 provided at least one of b, c or d is not 0;

z is the total number of groups of molecules on the array and is from about 2 to about 2000.

18. A method of claim 17 wherein the disease condition or disorder is cancer.
19. A method according to claim 17 wherein the disease condition or disorder is a non-neoplastic disorder.
20. A method according to claim 19 wherein the disease or condition is a non-neoplastic disorder of the immune system.
21. An assay device according to claim 20 wherein the disease or condition is selected from an autoimmune disease such as Type 1 diabetes, multiple sclerosis, myasthenia gravis, pernicious anaemia, psoriasis, rheumatoid arthritis, scleroderma and systemic lupus erythematosus, infection by a pathogen such as a virus including HIV-1, Hepatitis virus, Epstein-Barr virus (mononucleosis), a microorganism or a malarial parasite congenital immunodeficiency, adverse reaction following bone marrow or tissue transplantation or chronic fatigue syndrome.
22. A method according to claim 15 wherein the array comprises immunoglobulins in discrete regions of the solid support and the binding partners are antigens expressed on the surface of a normal or cancer cell or are released by a normal or cancer cell.
23. A method according to claim 22 wherein the array comprises the formula:

$$\left[\begin{array}{c} \left[q_{o_1} \right]_{e}^{m_1} \left[q_{o_2} \right]_{f}^{m_2} \dots \left[q_{o_k} \right]_{g}^{m_i} \end{array} \right]_y$$

wherein

q is an immunoglobulin specific for an antigen expressed on a normal cell or cancer cell or antigen released by a normal cell or cancer cell;

$m_1 m_2 \dots m_i$ represent members of the same immunoglobulin group which bind to different parts of the same antigen;

$o_1 o_2 \dots o_k$ represent different groups of immunoglobulins defined by specificity to different antigens.

e, f and g represent the number of different immunoglobulins within each of groups $o_1 o_2 \dots o_k$, respectively and wherein e, f and g may be the same or different and each is from 0 to 100 provided at least one of e, f or g is not 0;

y is the total number of groups of immunoglobulins on the array and is from about 2 to about 2000.

24. A method according to claim 22 wherein the immunoglobulins are monoclonal antibodies.

25. A method according to claims 23 or 24 wherein the immunoglobulins are specific for cluster of differentiation (CD) antigens and/or myeloid (MY) antigens or lymphoid (LY) antigens expressed on leukemic cells.

26. A method according to any one of claims 15 to 25 wherein the molecules immobilized on the solid support are in an arrangement in the array such that upon interaction between the molecules and the binding partners, a differential pattern of density provides an identifiable signal.

27. A method of treating cancer or a propensity to develop cancer in a human or non-

- 83 -

human animal, said method comprising obtaining a biological sample from said human or non-human animal and contacting said sample with an array of immunoglobulin molecules or functional derivatives or equivalents thereof immobilized to discrete regions of the solid support such that different discrete regions have specificity for different antigens and wherein the antigens are expressed on the surface of normal cells or cancer cells or are released by normal cells or cancer cells, and determining the binding pattern of the immobilized immunoglobulins to their respective antigens and then undertaking immunotherapy based on the expression of the antigens.

28. A method according to any one of claims 1 to 27 wherein the binding of a binding partner to an immobilized molecule is determined using a labelled antibody to the same binding partner or to a different partner associated with said first mentioned binding partner.

29. A method according to claim 28 wherein the labelled antibody is a fluorescently labelled antibody.

30. Use of an array of non-nucleic acid molecules capable of interaction with a respective binding partner putatively in a biological or chemical sample to determine the presence of a disease condition or disorder or a propensity for the development of a disease condition or disorder or to detect a microbe, virus, parasite or pathogen or to detect a peptide, polypeptide or protein in a phage display library.

31. A method for identifying a protein mimetic in a chemical or biological sample said method comprising contacting said sample with an array of immobilized molecules capable of binding to the protein for which a mimetic is sought and identifying the presence of a protein mimetic which binds to an immobilized molecule.

32. A method according to claim 31 wherein the immobilized molecules are immobilized immunoglobulins.

AMENDED SHEET
PCT/AU

- 84 -

33. A method according to claim 31 or 32 wherein the chemical sample is a synthetic or natural chemical library.

34. A method according to claim 31 or 32 wherein the biological sample is a phage display library.

35. A method according to claim 31 or 32 wherein the protein mimetic is capable of activating or antagonizing a B or T lymphocyte.